

Zacurate® 500DL

Zacurate

Finger Pulse Oximeter



User Manual

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Contents

| | |
|---|----|
| Letter to Users | 1 |
| Standard Packing List | 2 |
| Chapter 1 Precautions, Warnings and Symbol | 2 |
| 1.1 Precautions..... | 2 |
| 1.2 Warnings | 4 |
| 1.3 Symbol..... | 7 |
| Chapter 2 About This Product..... | 9 |
| 2.1 Overview | 9 |
| 2.2 Working Principles | 9 |
| 2.3 Intended Use | 10 |
| 2.4 Product Features | 10 |
| 2.5 Limitations..... | 11 |
| 2.6 Innovative features of the 500DL | 12 |
| 2.7 Schematic Structural Diagram..... | 13 |
| 2.8 Schematic Diagram of Display..... | 14 |

| | | |
|-----------|--|----|
| Chapter 3 | Operation Instructions | 15 |
| 3.1 | Battery Installation | 15 |
| 3.2 | Using the Lanyard | 16 |
| 3.3 | Taking SpO ₂ and Pulse Rate Readings..... | 17 |
| 3.4 | Tips to getting a good reading | 18 |
| Chapter 4 | Cleaning and Disinfection | 20 |
| Chapter 5 | Maintenance and Troubleshooting..... | 22 |
| 5.1 | Maintenance | 22 |
| 5.2 | Troubleshooting..... | 23 |
| Chapter 6 | Technical Description and Safety Type | 25 |
| 6.1 | Technical Specifications | 25 |
| 6.2 | Technical Description | 28 |
| 6.3 | Safety Type | 31 |
| 6.4 | Storage and Transportation | 31 |

Letter to Users

Thank you for choosing our Zacurate® 500DL Finger Pulse Oximeter. By listening intently and applying some of the changes as suggested by our customers, we hope you will find that the 500DL is a much more user-friendly, reliable and comfortable pulse oximeter than its predecessor. Before using this product, please read the user manual carefully and follow the instructions stated herein. Please also check that all accessories are complete as listed in the packing list and whether any component is damaged during shipping. If there is any damage and/or if you have any concerns, please contact us at cs@beyondmedshop.com or phone: 1-832-939-8290 with the following information:

1. Product model
2. Serial number of the product
3. Your contact information and address

The manual is updated periodically and the latest manual can be downloaded at

<http://www.beyondmedshop.com/products/500dl>

Standard Packing List

1. Pulse Oximeter.....1 PC
2. AAA Battery.....2 PCS
3. Lanyard.....1 PC
4. Silicone Cover.....1 PC
5. User Manual.....1 PC

Chapter 1 Precautions, Warnings and Symbol

1.1 Precautions

- Do not attempt to repair the pulse oximeter by yourself. Only certified engineers should maintain and repair it.
- Change the contact position between the oximeter probe and the finger periodically if your finger feels sore or is uncomfortable.
- Stop immediately if you have broken skin or the blood circulation of your finger is affected during prolonged use.
- This product is not designed to be used by newborn babies.
- Seek medical care if the measured value goes beyond the

normal range and you are sure that the device is not malfunctioning.

- The pulse oximeter uses infrared light (invisible to your eyes) to measure your SpO₂ level. Hence, please do not stare at the light emitting components of the oximeter to avoid potential eye damage and/or blindness.
- **This pulse oximeter is not a medical device and is not intended to diagnose and/or treat any medical condition or disease. It is intended for non-medical use by healthy people to monitor their pulse rate and blood oxygen levels. It is for sports and/or aviation use. People who need SpO₂ and pulse rate measurements because of a medical condition should consult with their physician.**

The following factors may affect the performance and accuracy of the oximeter:

- ◆ The oximeter is used in an environment with high-frequency devices, such as high-frequency electric knives and/or CT apparatuses.

- ◆ Ambient light intensity that is too bright. Hence, please avoid direct exposure to strong light (such as beams from operating lamps or sunlight) during measurement.
- ◆ The probe of the oximeter is placed on the same arm that a blood pressure cuff, arterial duct or intravenous injection is placed.
- ◆ The user suffers from hypotension, severe vascular atrophy, severe anemia, or low oxygen.
- ◆ The user is in sudden cardiac arrest or shock state.
- ◆ The user is wearing nail polish or artificial nails.

1.2 Warnings

Warning: Do not use the oximeter in an environment with any flammable gases, flammable anesthetic, or other flammable substances.

Warning: Keep unit and lanyard away from children as the included lanyard may pose as an entanglement or choking hazard to small children. Adult supervision is required; never leave children unattended with unit or lanyard.

Warning: Do not throw the batteries into fire, as that may cause an explosion.

Warning: Do not attempt to charge the included batteries, as that could cause leakage, fire disaster, or even explosion. Dispose the used batteries in accordance to the local laws and regulations.




Warning: Do not use the oximeter in an MRI or CT environment.



Caution: Do not operate the oximeter if it is wet. Avoid moving the oximeter from a cold to a hot and humid environment.

Caution: Install the batteries properly before powering on the oximeter for normal use. Please remove the batteries if you are not planning to use the oximeter for an extended period of time.

Caution: Close the battery cover when the device is in use.

1.3 Symbol

| Symbol | Meaning |
|---|--------------------------------------|
|  | BF-type application part |
|  | Caution: Please refer to this manual |
| %SpO ₂ | Symbol of oxygen saturation |
| ♥ /Min | Symbol of pulse rate |
|  | Manufacturer information |

| Symbol | Meaning |
|---|---|
|  | Temperature limitation |
|  | Electrical waste materials should be sent to dedicated collection points for recycling. |
| Warning | A personal injury or device damage may result if the device is not used correctly. |
| Caution | Important information on the proper usage of the device. |
| Attention | Necessary information to protect this device against damage. |

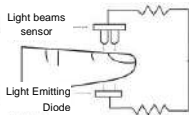
Chapter 2 About This Product

2.1 Overview

SpO₂ stands for peripheral capillary oxygen saturation. Oxygen saturation is defined as the ratio of oxyhemoglobin (HbO₂) to the total concentration of hemoglobin (i.e. Oxyhemoglobin + reduced hemoglobin) present in the blood. It is an important physiological parameter involved in respiration and circulation. The Pulse Oximeter feature herein is small, portable, non-invasive and easy to use. The user only needs to insert a finger into the chamber to measure his/her SpO₂ level and pulse rate.

2.2 Working Principles

Oxygenated blood absorbs light preferentially at 905nm (near infrared light), whereas deoxygenated blood absorbs light preferentially at 660nm (red light). A pulse oximeter works by passing a beam of red and infrared light through a pulsating capillary bed and then measure the amount of red and infrared light emerging from the tissues via a sensor. To



improve accuracy, the 500DL uses a proprietary algorithm to collect data from pulsatile arterial blood and excludes local noise from the tissues. The relative absorption of light by oxyhemoglobin (HbO) and deoxyhemoglobin is then calculated according to the Beer-Lambert's law and a quantitative measurement of the users' oxyhemoglobin status i.e. Oxygen saturation level (SpO₂) is derived.

Due to the sensitivity of the pulse oximeter, finger should be kept stationary during measurement. It is recommended that you use this device for measurement before or after sports. Do not use for continuous monitoring.

2.3 Intended Use

The Zacurate® 500DL Finger Pulse Oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (PR) of adult and children (>2 years old).

2.4 Product Features

- Lightweight, portable and easy to use
- Large LED screen for easy reading
- Low Battery indicator
- Automatic shut down if no signal is detected after 8seconds.

- The device is equipped with two 1.5V AAA batteries, which will allow the pulse oximeter to operate for approximately 30 hours.

2.5 Limitations

The pulse oximeter works by measuring the amount of oxygenated hemoglobin in your blood over a period of time. Spot check pulse oximeter takes 1-2 readings every second and takes an average of 4-6 readings before displaying the result. Hence, you will have to wait at least 4-6 seconds before a result will be displayed on the monitor. If the pulse oximeter fails to detect blood flow for the first few seconds, the results will be delayed accordingly.

The pulse oximeter does not work for people with naturally small fingers or low peripheral blood flow. This is because the pulse oximeter could not detect enough blood for a measurement. Please note that prolonged use of a pulse oximeter, hypotension, vasoconstriction, hypothermia and certain medications can lead to low or restricted blood flow. Nail polish can also impede the pulse oximeter from taking a reading. To know how much blood flow is being detected by the pulse oximeter, you will need a model that can display the plethysmograph (Model 500D). Finally, it is generally

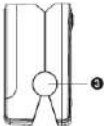
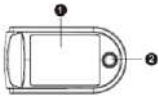
accepted that the saturation percentage is unreliable on the steep part (around 60 mm Hg) of the oxyhemoglobin dissociation curve.

2.6 Innovative features of the 500DL

The 500DL is designed to address and alleviate some of the above problems by

- 1) Increasing the sensitivity of the sensor to allow user to measure his/her SpO₂ levels and Pulse Rate (PR) even at low blood perfusion.
- 2) Using a self-adjusting smart spring system to fit user's finger snugly but not too tight as to impede blood flow.
- 3) Using soft, hypoallergenic medical grade silicone in the finger chamber to minimize discomfort to user's finger.
- 4) Using solid ABS plastic to block ambient light from reaching the sensor so that the signal to background ratio and accuracy of measurement is dramatically increased.

2.7 Schematic Structural Diagram




- 1** LED screen
- 2** Power-on key
- 3** Shaft housing
- 4** Battery cover

2.8 Schematic Diagram of Display

The following figure shows the information display on the LED screen of the Oximeter in normal detection state:



Note: The display shows all segments during an internal self-check when powered on.

When the battery icon  flickers continuously on the LED screen, the battery is low and needs to be replaced.

Chapter 3 Operation Instructions

3.1 Battery Installation

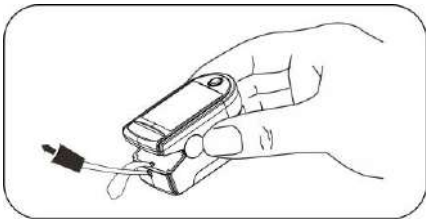
Open the battery compartment. Install two AAA batteries by matching the plus (+) and minus (-) signs in the compartment. Slide battery cover back until it snaps in place.

Note: Incorrectly installed batteries may damage the device.



3.2 Using the Lanyard

Remove the silicone cover. Thread the thin end of the lanyard through the lanyard hole, thread the coarse end of the lanyard through the thin end of the lanyard, and tighten the lanyard. Put the silicone cover back on.

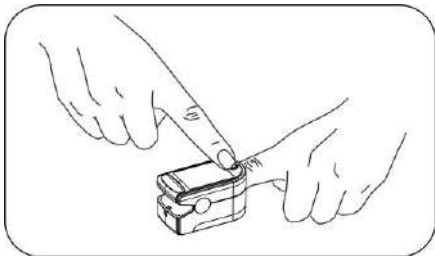


3.3 Taking SpO₂ and Pulse Rate Readings

1. Insert one of your fingers into the finger chamber of the pulse oximeter.

Note: The fingernail should be facing the top chamber (which contains the sensor). Finger should also be inserted completely into the chamber. Otherwise, measurement will be inaccurate.

2. Press the power-on key to turn the pulse oximeter on.
3. Keep your hand and finger still for the reading. It is recommended that you do not move your body while taking a reading.
4. Once the reading stabilizes, read the measured values of the oxygen saturation level and pulse rate on the LED screen.
5. The pulse oximeter will automatically shut down in 8 seconds after finger is removed from the chamber or if no signal is detected by the device.



Note: Before each use, it is recommended to clean finger and the silicone padded finger chamber. The silicone is non-toxic, soft and hypoallergenic.

3.4 Tips to getting a good reading

1. Make sure that your finger is inserted deep into the chamber so that the fingertip is placed directly in between the LED light source and the LED sensor.

2. Avoid making any body movement, especially your finger while taking measurement.
3. Long fingernails may obstruct the light sensor and prevent accurate measurement. Please keep fingernails short while using the device.
4. Excessive ambient infra-red light, especially in an overly bright lit room, can interfere with the sensor, preventing an accurate measurement.
5. Poor blood circulation can affect oximeter readings. Warm your hands and fingers before taking measurements. Note that the pulse oximeter is measuring your SpO₂ and PR based on your blood flow. If the blood flow in your finger drops below a certain level, the pulse oximeter will not be able to get a reading.
6. Some people with medical conditions such as anemia, hypotension and hypothermia may experience inaccurate reading during use. In such case, we suggest that you consult a physician.
7. The pulse bar graph which indicates pulse strength can be used to determine the reliability of a reading. If the height of the pulse bar is less than 30%, this indicates signal inadequacy and the displayed SpO₂ and Pulse Rate value is potentially incorrect. Readjust your finger to ensure proper placement.

Chapter 4 Cleaning and Disinfection

It is recommended to clean the pulse oximeter regularly. The pulse oximeter can be disinfected as needed.

To clean, use a soft cloth lightly dampened with water.

To disinfect, use a soft cloth lightly dampened with isopropyl alcohol.

1. Make sure that the device is off and remove the batteries.
2. Wipe the outer surface of the device and the finger chamber using lightly dampened soft cloth.
3. Allow the device to air dry thoroughly before use.

Caution: Do not use any strong dissolving agent such as acetone.

Caution: Do not rub the body of the device using materials such as steel wire balls or polished metal objects.

Caution: Do not immerse or soak any part of the device in any liquid.

Caution: Do not pour or spray liquid onto the device.

Caution: Do not allow any liquid to seep into the device during cleaning.

Caution: Do not disinfect the device using high-temperature and/or high-pressure disinfecting gas.

Chapter 5 Maintenance and Troubleshooting

5.1 Maintenance

- Remove the batteries from the battery compartment if the pulse oximeter will not be used for an extended period of time.
- Replace the batteries if they are low on power.
- Clean the pulse oximeter and the fingertip before every use to ensure accurate reading.
- Store the pulse oximeter between -13°F and 158°F (-25°C and +70°C) and at humidity levels no greater than 93%.
- Periodically check the pulse oximeter for damage.
- Do not use the pulse oximeter in an environment with flammable gases and/or where the temperature or humidity is excessively high or low.

5.2 Troubleshooting

| Problems | Possible Cause | Solution |
|---|--|--|
| The oximeter fails to display the blood oxygen saturation levels and/or pulse rate. | <ol style="list-style-type: none"><li data-bbox="365 221 572 330">1. Finger is not inserted correctly.<li data-bbox="365 352 619 461">2. User's blood flow is too low to be measured. | <ol style="list-style-type: none"><li data-bbox="681 221 935 407">1. Make sure that finger is placed right in between the sensor and LED lights.<li data-bbox="681 429 914 614">2. Make sure that nothing is restricting the user's blood flow. |

| Problems | Possible Cause | Solution |
|---|--|---|
| <p>The SpO₂ or Pulse Rate reading is unstable or fluctuates.</p> | <ol style="list-style-type: none"> 1. Finger may not be inserted deep enough. 2. Excessive body movement. 3. Pulse is too weak. | <ol style="list-style-type: none"> 1. Insert finger deep into the chamber. 2. Please do not move during measurement. 3. Warm finger or switch finger. |
| <p>The oximeter cannot be powered on.</p> | <ol style="list-style-type: none"> 1. Batteries are drained. 2. Batteries are incorrectly installed. 3. The oximeter is damaged or defective. | <ol style="list-style-type: none"> 1. Replace the batteries. 2. Please refer to 'Battery Installation' instruction. 3. Please contact the distributor. |

| Problems | Possible Cause | Solution |
|--|---|--|
| The display screen turns off suddenly. | <ol style="list-style-type: none"> 1. The oximeter powers off automatically when no signal is detected for more than 8 seconds. 2. Batteries are drained. | <ol style="list-style-type: none"> 1. This is normal. Just turn the oximeter on again. 2. Replace the batteries. |

Chapter 6 Technical Description and Safety Type

6.1 Technical Specifications

1. Dimensions: 58.0 mm (Width) × 32.0 mm (Depth) × 33.2 mm (Height) (Approximately 2.28 inch X 1.25 inch X 1.30 inch)
Weight: 49.5 g/1.7 oz (including the weight of two AAA batteries)
2. Peak wavelength range of the light emitted by the probe: red light 660 nm ± 3nm; infrared light 905 nm ± 10nm.

3. Maximum optical output power of the probe: 2.4 mW for infrared light (905 nm).3.2mW for infrared light (660nm)
4. Working power supply and current

| | |
|-----------------------|-------------------------|
| Internal Power Supply | Two 1.5 V dry batteries |
| Working Current | 35 mA |

5. Normal working condition

| | |
|----------------------|-----------------------------|
| Working Temperature | 5°C to 40°C (41°F to 104°F) |
| Relative Humidity | 15% to 93%, non-condensing |
| Atmospheric Pressure | 700 hPa to 1060 hPa |

| | |
|---------------|----------|
| Rated Voltage | DC 3.0 V |
|---------------|----------|

6. Technical parameters

| Parameter | | Value |
|----------------------|-------------------|---|
| Display range | Oxygen saturation | 0% to 100% |
| | Pulse rate | 0 bpm to 250 bpm |
| Resolution | Oxygen saturation | 1% |
| | Pulse rate | 1 bpm |
| Measurement accuracy | Oxygen saturation | $\pm 2\%$ (70% to 100%) No requirement ($\leq 69\%$) |
| | Pulse rate | ± 2 bpm (30 to 99 bpm) $\pm 2\%$ (100 to 250 bpm) |

7. Capability to resist ambient light interference

Comparing the measured value of oxygen saturation taken in indoor

natural light or other illumination sources to that taken in darkroom condition, the deviation is smaller than $\pm 1\%$.

6.2 Technical Description

1. Oxygen Saturation Accuracy

The accuracy is $\pm 2\%$ (in the absence of movement) between 70% to 100%.

Note: The oxygen saturation accuracy is a root mean square of the difference. The measured values of the device are distributed according to statistical probability. Only about two thirds of the measured values of the Pulse Oximeter fall within $\pm 2\sigma$ of the measured values of a carbon-monoxide-blood-gas analyzer.

2. Determination of Oxygen Saturation Accuracy

The claimed oxygen saturation is supported by coverage of the entire range of clinical research measurements.

3. Data Collection

In the clinical test process, data points are recorded with comparable density in the entire claimed range.

4. Data Analysis

For each claimed range, the oxygen saturation accuracy of the Pulse Oximeter should be represented in the form of mean root square of the difference between the measured values of oxygen saturation and the reference value. The formula is as follows:

$$\text{Arms} = \sqrt{\frac{\sum_{i=1}^n (SPO_{2i} - S_{Ri})^2}{n}}$$

Arms: accuracy

n : test sample quantity

SPO_{2i} : measured value of pulse oxygen saturation during the first measurement using the finger pulse Oximeter

S_{Ri} : reference value of pulse oxygen saturation during the i^{th} measurement using the carbon-monoxide-blood-gas analyzer

5. Characteristics of Population under Clinical Research

The summary clinical research report for evaluating SpO₂ accuracy should state whether the tested subject suffers from disease or is healthy, and should state the skin color, age, and gender of the tested subject.

6. Data updating interval: The display data updating interval is 1 second.

7. When the signal detected by the Pulse Oximeter is incomplete or weak, the readings of the oxygen saturation and pulse rate on the LED screen are "--" and "--".

Note: The functional tester shall not be used to evaluate the accuracy of the probe of the Pulse Oximeter or the accuracy of the pulse oxygen monitor

Note: The Pulse Oximeter has a specific calibration curve, and is precise for the combination of the mainframe and probe of the Pulse Oximeter. If the functional tester can measure the portion of overall errors of the mainframe-probe system of the Oximeter attributable to the mainframe of the Oximeter, the functional tester can test the accuracy of a Pulse Oximeter that duplicates the calibration curve.

Note: The product does not provide alarm function and is not suitable for continuous long-term monitoring. When the probe of the Oximeter fails, the Oximeter displays "--" and "--".

6.3 Safety Type






Anti-electric-shock type: internal power supply device

Anti-electric-shock degree: BF-type application part

Running mode: continuous operation

Liquid-intrusion protection class: IP22

6.4 Storage and Transportation

| | | | |
|--|---|---|---|
|  | Storage temperature and relative humidity |  | Atmospheric pressure: 500hpa to 1060hpa |
|  | Limited height: 15 stories |  | Place upward |
|  | Guard against moisture | | |

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